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13

14 UNITED STATES DISTRICT COURT
15 DISTRICT OF CALIFORNIA

16 ADRIANN GEORGES,

17 Plaintiff,

18 vs.

19 NOVARTIS PHARMACEUTICALS
CORP., et al.,

20 Defendants.
21

Case No. 2:06-cv-5207-SJO-VBK

DEFENDANT'S POINTS AND
AUTHORITIES IN SUPPORT OF
MOTION FOR JUDGMENT AS A
MATTER OF LAW OR, IN THE
ALTERNATIVE, FOR A NEW
TRIAL OR AMENDED JUDGMENT

22 Date: December 9, 2013
Time: 10:00 a.m.
Judge: Hon. S. James Otero
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INTRODUCTION

2 Novartis Pharmaceuticals Corporation (“NPC” or “Novartis”) hereby moves
3 for judgment as a matter of law, pursuant to Federal Rule of Civil Procedure 50(b),
4 or, in the alternative, for a new trial, pursuant to Federal Rule of Civil Procedure
5 59(a). NPC is entitled to judgment as a matter of law because Plaintiff failed to
6 proffer sufficient evidence at trial that NPC breached any duty to warn before
7 Adriann Georges developed osteonecrosis of the jaw (“ONJ”) or that any alleged
8 inadequate warning for its drug Zometa® was a proximate cause of Ms. Georges’
9 ONJ. NPC is also entitled to judgment as a matter of law because the specific
10 causation opinion of Ms. Georges’ expert, Dr. Eric Sung, was based upon an
11 unreliable “differential diagnosis” that should have been excluded.

In the event the Court declines to grant NPC judgment on all claims, NPC moves pursuant to Rule 59 for a new trial based upon the trial court's improper admission of evidence on a "lost chance of improved outcome theory" that was abandoned by Ms. Georges in response to a pre-trial motion in limine and is, in any event, impermissible under California law. Finally, NPC moves, in the alternative, for an amended judgment reducing Plaintiff's award for past and future economic damages.¹

BACKGROUND

20 Aredia® and Zometa® are intravenous bisphosphonate medications
21 prescribed to individuals with, among other things, cancers that have metastasized
22 to bone. 4/10/13 Trial Tr. 212:9-11, 213:2-6. The drugs are prescribed to prevent
23 devastating skeletal complications that frequently occur in patients with such
24 cancers. 4/18/13 Trial Tr. 139:24-140:6. These complications include pathologic
25 fractures, spinal cord compression (which can result in paralysis), and

¹ NPC has concurrently filed an Appendix of (1) the judgments, orders, and transcripts from other cases and (2) the transcripts and exhibits from the *Georges* trial that are cited in these points and authorities.

1 hypercalcemia of malignancy (an elevation of calcium in the blood which can prove
2 fatal). 4/18/13 Trial Tr. 138:15-24. As plaintiff's own expert, Dr. Robert Marx,
3 testified, the drugs are "extremely effective in halting the progression of both small
4 and large bone metastases." 4/16/13 Trial Tr. 200:7-10. In fact, he has written that
5 these drugs "have dramatically extended life, reduced skeletal complications,
6 reduced pain, and thus improved the quality of life for individuals with metastatic
7 bone cancer." 4/16/13 Trial Tr. 199:25-200:6. Since 1991, the United States Food
8 and Drug Administration has approved these medications as safe and effective on
9 six separate occasions and, each time, approved the labeling. 4/10/13 Trial Tr.
10 211:10-12.

11 Plaintiff Adriann Georges was diagnosed with metastatic breast cancer in
12 1999. Almost immediately thereafter, her oncologist, Dr. Waisman prescribed
13 Aredia® in order to "decrease [the] risk of pathologic fractures," "improve her bone
14 pain," and "decrease the likelihood of distant metastatic disease," i.e., the spread of
15 the cancer to other organs. 4/18/13 Trial Tr. 54:8-55:8. In March 2000, Ms.
16 Georges' jaw problem began, and it was subsequently determined to be
17 osteonecrosis of the jaw ("ONJ"). 4/15/2013 Trial Tr. 119:10-15 ("first quarter of
18 2000"); PX-1157 at 28 (noting "spontaneous exposure of mylohyoid prominence"
19 on March 1, 2000). In March 2002, Dr. Waisman switched Ms. Georges from
20 Aredia® to Zometa® because of evidence that Zometa® was more effective than
21 Aredia® in reducing devastating skeletal complications and for patient convenience
22 due to the shorter infusion time. 4/18/13 Trial Tr. 69:11-21; DX-2497 at 2032. Ms.
23 Georges received her final infusion of Zometa® in March 2005. DX-2497 at 1696,
24 1975.

25 Ms. Georges filed this lawsuit in 2006. She alleged that NPC was liable due
26 to an alleged failure to provide adequate warnings of the risk of ONJ and for
27 concealing this risk. Trial began on April 9, 2013. Following the close of
28 plaintiff's case on April 19, 2013, NPC filed a Rule 50(a) Motion for Judgment as a

1 Matter of Law. See ECF No. 304. On April 19, 2013, NPC rested and renewed its
2 Motion for Judgment as a Matter of Law. 4/19/13 Trial Tr. 22:12-16. On April
3 24, 2013, the jury returned a verdict in favor of plaintiff on all three of her claims.
4 On September 24, 2013, judgment was entered for plaintiff for compensatory
5 damages in the amount of \$2,162,000. See ECF No. 349.

6 **STANDARD**

7 Pursuant to rule 50(b), if a party “has been fully heard on an issue” at trial
8 and the court concludes that “a reasonable jury would not have a legally sufficient
9 evidentiary basis to find for the party on that issue,” the court may “direct the entry
10 of judgment as a matter of law” for the defendant. Fed. R. Civ. P. 50(a)(1) &
11 (b)(3). Plaintiff can survive a rule 50 motion only if the evidence actually presented
12 at trial raises a material issue of fact for the jury. *See Los Angeles Memorial*
13 *Coliseum Comm'n v. NFL*, 726 f.2d 1381, 1387 (9th cir. 1984) (“when there is no
14 substantial evidence to support a claim . . . The court must direct a verdict.”)

15 Pursuant to Rule 59, the court may in the alternative grant a motion for a new
16 jury trial on all or some of the issues “for any reason for which a new trial has
17 heretofore been granted in an action at law in federal court.” Fed. R. Civ. P.
18 59(a)(1)(A). A district court may grant a new trial where, among other
19 circumstances, the verdict is against the clear weight of the evidence or is based on
20 false evidence, or to prevent a miscarriage of justice. *Silver Sage Partners, Ltd. v.*
21 *City of Desert Hot Springs*, 251 F.3d 814, 819 (9th Cir. 2001); *Landes Constr. Co.*
22 *v. Royal Bank of Canada*, 833 F.2d 1365, 1371 (9th Cir. 1987). Rule 59(e) also
23 permits the trial court to alter or amend the judgment.

24 **ARGUMENT**

25 **I. NPC Is Entitled To Judgment As A Matter Of Law.**

26 NPC is entitled to judgment as a matter of law on all of plaintiff's claims for
27 three reasons. First, Plaintiff failed to present sufficient evidence that NPC
28 breached any duty to warn about the then-unrecognized risk of ONJ prior to Ms.

1 Georges' alleged development of ONJ in March 2000. Second, Plaintiff failed to
2 present sufficient evidence that NPC's alleged failure to warn was a substantial
3 factor in causing Ms. Georges' injury. In other words, Plaintiff offered no evidence
4 that even if NPC had provided an "adequate" warning, it would have avoided her
5 jaw injury. Third, Plaintiff failed to present admissible expert testimony that her
6 use of Aredia® and Zometa® was a substantial factor in the development of her
7 ONJ. The opinions of Dr. Sung – her only witness on this issue – are based upon
8 an unreliable methodology and insufficient facts; as such, they should be stricken
9 from the trial record.

10 **A. Plaintiff failed to present sufficient evidence that NPC breached a
11 duty to warn.**

12 All of Plaintiff's claims, whether couched as failure to warn or concealment,
13 are premised upon her contention that NPC failed to warn of the potential risk of
14 ONJ with Aredia® and Zometa® treatment. Under California law, a prescription drug
15 company has no duty to warn of an alleged risk unless the risk is "known or
16 reasonably scientifically knowable at the time of distribution." *Brown v. Superior
17 Court*, 44 Cal. 3d 1049, 1069, 245 Cal. Rptr. 412, 424 (1988); *see also id.* at 1072
18 n.14 (holding that a plaintiff may not heighten the defendant's duty to warn through a
19 breach of warranty claim); *see also* Judicial Council of California Civil Jury
20 Instructions, Instruction No. 1205 (plaintiff must prove alleged risk was known or
21 knowable "in light of the scientific and medical knowledge that was generally
22 accepted in the scientific community").² Moreover, "California law does not require
23

24 ² Plaintiff's burden with regard to her concealment claim was even greater, as
25 California law required her to establish that NPC *actually* knew of and
26 *intentionally* concealed the alleged risk of ONJ. *See Hahn v. Mirda*, 147 Cal. App.
27 4th 740, 748, 54 Cal. Rptr. 3d 527, 532 (2007) (stating elements of fraudulent
law on Plaintiff's concealment claim). Accordingly, each of NPC's arguments with
regard to Plaintiff's failure to warn claim likewise requires judgment as a matter of

1 [a manufacturer defendant] to know more than any other expert at any given point in
2 time.” *Todd v. Stryker Corp.*, No. 09-1509, 2012 WL 2922727, at *6 (E.D. Cal. May 1,
3 2002). Thus, in order to establish that NPC breached a duty to warn in this case,
4 Plaintiff was required to establish that NPC knew or reasonably should have known
5 of the risk of ONJ before Ms. Georges developed ONJ in the first quarter of the year
6 2000. *See* 4/15/2013 Trial Tr. 119:10-15 (“first quarter of 2000”); PX-1157 at 28
7 (noting “spontaneous exposure of mylohyoid prominence” on March 1, 2000).

8 As another federal district court in the Ninth Circuit recently concluded in
9 granting summary judgment to NPC based upon the same factual record, Plaintiff
10 has no such evidence. *See D’Agnese v. Novartis Pharm. Corp.*, ____ F. Supp. 2d
11 ___, No. CV-12-749, 2013 WL 3335203, at *10 (D. Ariz. July 2, 2013). The trial
12 record establishes that NPC received its very first case report of ONJ on December
13 5, 2002. *See* PX-413. There is no evidence that NPC actually knew of any risk of
14 ONJ before this date, and the only other “safety signals”³ by which Plaintiff’s expert
15 Dr. Parisian opined NPC “should have known” of the risk did not occur until 2002:

- 16 • Dr. Ruggiero’s question to Peter Tarassoff in April 2002 regarding
17 whether bisphosphonates cause osteonecrosis. PX-411; 4/10/2013
18 Trial Tr. 156:21- 157:24.
- 19 • Dr. Marx’s pathology textbook, which described a painless avascular
20 necrosis, and which purportedly became available to the public in
21 July 2002. PX-812; 4/10/2013 Trial Tr. 185:8-24; 4/16/2013 Trial Tr.
22 151:9- 12.
- 23 • Dr. Ruggiero’s report of 26 patients during the Harrigan Society
24 meeting at NYU on December 7, 2002. PX-253; 4/10/2013 Trial Tr.
25 153:16-155:3.

26 _____
27 ³ Dr. Parisian testified a safety signal is “is some kind of a signal of something
28 that’s new or different about your drug that you need to go and investigate.”
4/10/2013 Trial Tr. 129:24-130:1.

- 1 • Dr. Marx's September 2003 Letter to the Editor. PX-1028;
2 4/10/2013 Trial Tr. 166:24-168:15.

3 All of these purported safety signals post-date Ms. Georges' alleged development
4 of ONJ by at least two years. Accordingly, even assuming that these "signals"
5 triggered NPC's duty to warn at the time, a new warning could not have prevented
6 Ms. Georges' jaw injury.

7 Although Dr. Parisian offered additional criticisms of NPC pertaining to a
8 Gotcher & Jee article, osteopetrosis, and the potential ONJ cases from the clinical
9 trials, Dr. Parisian did not testify that any of these items were safety signals that
10 triggered a duty to investigate or to warn about ONJ. With regard to the Gotcher &
11 Jee article and osteopetrosis, Dr. Parisian criticized NPC only because the company
12 did not submit these materials to the FDA. *See* 4/10/2013 Trial Tr. 137:17-141:19,
13 141:20- 144:22. With regard to the clinical trials, Dr. Parisian observed that NPC
14 identified six potential cases of ONJ retrospectively in 2005 using a key word search
15 of the ARGUS database. *See* PX-509; 4/11/2013 Trial Tr. 42:25-52:12. Nowhere
16 in the record is there any evidence that NPC should have identified the potential
17 cases earlier, much less before Ms. Georges developed her jaw injury, because it
18 was undisputed that (and as Dr. Parisian conceded): none of the six identified cases
19 were reported as being drug related; none of them were reported as serious adverse
20 events; and none of them were actually identified as cases of osteonecrosis of the
21 jaw. 4/11/2013 Trial Tr. 68:6-73:11.

22 In *D'Agnese*, the court squarely rejected plaintiffs' attempt to rely on this
23 same evidence as providing a basis for a breach of duty to warn. The court
24 explained:

25 Plaintiffs have not pointed to any evidence, including any
26 testimony, suggesting that based on one study and six
27 possible cases of ONJ in a clinical trial, Defendant's
28 actions fell below the acceptable standard of care, *i.e.*,

1 what a reasonably prudent manufacturer would have
2 known and warned about. Likewise, Plaintiffs have not
3 pointed to any evidence or testimony that, in light of this
4 article and six possible cases of ONJ in the clinical
5 trial[s], ONJ was a knowable risk of using Aredia® in
6 light of the generally recognized and prevailing best
7 scientific and medical knowledge available at the time of
8 manufacture and distribution.

9 2013 WL 3335203, at *9. The court then held under an Arizona law standard
10 identical in all material respects to California law “that claims based on inadequate
11 warnings cannot be based on the information now available regarding connections
12 between ONJ and bisphosphonates, but rather must be based on what was knowable
13 at the time a warning should have allegedly been given.” *Id.*; see also *Brown*, 44
14 Cal. 3d at 1069, 245 Cal. Rptr. at 424; *Valentine v. Baxter Healthcare Corp.*, 68 Cal.
15 App. 4th 1467, 1483-84, 81 Cal. Rptr. 2d 252, 263 (1999) (“a reasonable
16 manufacturer would not be charged with knowing more than what would come to
17 light from the prevailing scientific and medical knowledge”) (affirming directed
18 verdict for defendant). The court accordingly held that NPC had not breached any
19 duty to warn at the time of the plaintiff’s prescription with Aredia®. The same
20 holding is warranted here.⁴

21 In September 2003, NPC became the first manufacturer of bisphosphonates
22 to place a warning on its label regarding the risk of ONJ. 4/10/2013 Trial Tr. 193:21-
23 23. This was the same month Dr. Marx published his Letter to the Editor in the
24 Journal of Oral and Maxillofacial Surgery, in which Dr. Marx described ONJ as “a
25 heretofore unrecognized and unreported serious adverse affect.” PX-1028. At

27 ⁴ The plaintiff in *D’Agnese* was initially prescribed Aredia® in 1996. 2013 WL
28 3335203, at *5. Ms. Georges did not present any evidence at trial that any
information regarding the risk of ONJ arose between 1996 and 2000.

1 trial, Dr. Marx testified unambiguously that, at the time of this September 2003
2 publication, the risk of ONJ with bisphosphonates was not generally accepted in the
3 medical or dental communities:

4 Q: In September of 2003, it was not generally -- I'm
5 sorry. The possibility that Aredia and Zometa
6 were associated with osteonecrosis of the jaw wasn't
7 generally accepted any place in the medical, dental
8 or scientific community as of the date you
9 published that article. Isn't that correct?

10 A: Well, it was the first article -- you can't -- of
11 course it can't be accepted. It was the first article
12 to come out.

13 4/16/2013 Trial Tr. 231:8-14.

14 Accordingly, Plaintiff has not presented any evidence supporting her claim that
15 NPC had a duty to warn of the risk of ONJ prior to Ms. Georges' jaw injury, and
16 judgment should be entered in favor of NPC as a matter of law.

17 **B. Plaintiff failed to present sufficient evidence that NPC's alleged
18 failure to warn was a substantial factor in causing her injury.**

19 In addition to establishing that NPC breached a duty to warn, Plaintiff was
20 required to prove proximate causation, *i.e.*, that "the inadequacy or absence of the
21 warning caused the plaintiff's injury." *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984,
22 991 (C.D. Cal. 2001) (applying California law), *aff'd*, 358 F.3d 659, 660-61 (9th
23 Cir. 2004). This means that Plaintiff must prove that if NPC had provided a
24 different warning regarding ONJ: (1) Ms. Georges or her prescribing physician
25 would have altered her treatment in some manner *and* (2) this change would have
26 prevented her jaw injury. 4/22/13 Trial Tr. 30:22-31:7 (jury instruction explaining
27 that "[i]n order to prevail on her claim, Ms. Georges must prove that if Novartis
28 gave a different warning or disclosed different information, Ms. Georges would not

1 have developed her jaw injury”); *see also Motus*, 196 F. Supp. 2d at 991 (“A
2 plaintiff asserting causes of action based on a failure to warn must prove not only
3 that no warning was provided or the warning was inadequate, but also that the
4 inadequacy or absence of the warning caused the plaintiff’s injury.”); *see also*
5 *Latiolais v. Merck & Co.*, 302 F. App’x 756, 757, 2008 WL 5157705 (9th Cir.
6 2008).⁵

7 Because prescribing physicians recognize the undisputed and life-extending
8 benefits of Aredia® and Zometa® to their patients, a failure of proximate causation
9 has tended to trump plaintiffs’ claims in the Aredia®/Zometa® litigation. Indeed,
10 plaintiffs’ inability to establish proximate causation has repeatedly resulted in
11 judgments for NPC as a matter of law. Recently, for example, following a two-
12 week trial in which the plaintiff likewise failed to proffer sufficient evidence of
13 proximate causation, another federal district court in California granted NPC’s Rule
14 50(a) motion for judgment as a matter of law. *See Hill v. Novartis Pharm. Corp.*,
15 06:CV-0939, Final Judgment and Incorporated Oral Ruling (E.D. Cal. June 26,
16 2013) (Ex. 1).⁶ Further, “[f]ailure to establish proximate cause has resulted in
17 summary judgment in a number of other remanded Aredia® and Zometa® cases”
18 including two other cases within the Ninth Circuit. *Payne v. Novartis Pharm.*
19 *Corp.*, No. 1:12-CV-77, 2013 WL 4779571, at *6 (E.D. Tenn. Sept. 6, 2013); *see*
20 *D’Agnese*, 2013 WL 3335203, at *9-10; *Luttrell v. Novartis Pharm. Corp.*, 894 F.
21 Supp. 2d 1324, 1344-46 (E.D. Wash. 2012); *Ingram v. Novartis Pharm. Corp.*, 888

22
23 ⁵ Under California law, these elements of causation must be proven to a
24 reasonable degree of medical probability. “The law is well settled that in a personal
25 injury action causation must be proven within a reasonable medical probability
26 based upon competent testimony. Mere possibility alone is insufficient to establish
a prima facie case.” *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 402, 209
Cal. Rptr. 456, 460-61 (1985). If “speculation or conjecture” is required to prove
“proximate cause[,] then the granting of nonsuit is proper.” *Id.*

27 ⁶ In order to provide a full appellate record, the district court nonetheless allowed
28 the jury to deliberate. The jury subsequently returned a verdict in favor of NPC.
The plaintiff did not appeal.

1 F. Supp. 2d 1241, 1245-46 (W.D. Okla. 2012); *Zimmerman v. Novartis Pharm.*
2 *Corp.*, 287 F.R.D. 357 (D. Md. 2012); *Eberhart v. Novartis Pharm. Corp.*, 867 F.
3 Supp. 2d 1241, 1254 (N.D. Ga. 2011).

4 NPC is likewise entitled to judgment as a matter of law in this case. Plaintiff
5 posited two alternative theories in an effort to establish that the alleged inadequate
6 warnings proximately caused her ONJ: (1) that Ms. Georges would not have been
7 prescribed Aredia® or Zometa® if NPC had issued an adequate warning before she
8 commenced with bisphosphonates; and (2) that Dr. Waisman would have
9 recommended a pre-treatment dental exam if NPC had adequately warned, and such
10 an exam would have avoided her ONJ. Plaintiff failed, however, to present sufficient
11 evidence to support her burden of proof on either of these theories.

12 With regard to the first theory, Dr. Waisman clearly testified that, even if he
13 knew everything he knows now about ONJ, he still would have prescribed Aredia® to
14 Ms. Georges in 1999, when she was diagnosed with metastatic breast cancer, and he
15 still would have prescribed Zometa® to Ms. Georges in 2002. *See* 4/18/2013 Trial
16 Tr. 84:6-13. Dr. Waisman’s testimony thus forecloses a “plaintiff-would-not-have-
17 been-prescribed-the-drug” theory of proximate causation. *See Motus*, 196 F. Supp.
18 2d at 997-98 (“most cases do not permit a plaintiff to get past summary judgment
19 where the doctor made unequivocal statements . . . that adequate warnings would not
20 have affected his or her decision to prescribe a drug”); *D’Agnese*, 2013 WL
21 3335203, at *9 (granting summary judgment to NPC in Aredia®/Zometa® case where
22 plaintiff failed to establish that doctor would have changed decision to prescribe drug
23 if warned of ONJ risk); *Ingram*, 888 F. Supp. 2d at 1246-47 (same). In fact, Dr.
24 Waisman continued to prescribe Zometa® *after* learning about the possible
25 association with ONJ, and for several months *after* she too learned about it, Ms.
26 Georges continued to receive the medication. PX 1124-PC; 4/18/13 Trial Tr. 168:11-
27 20; DX 2497 at 1696, 1698, 1701, 1984-85; *see D’Agnese*, 2013 WL 3335203, at *9
28 (granting summary judgment where prescriber continued to prescribe Zometa® and

1 plaintiff continued to take medication after learning about possible risk of ONJ).

2 Under the learned intermediary doctrine, NPC's duty to warn runs only to the
3 prescribing physician. *Motus*, 358 F.3d at 661.⁷ Ms. Georges accordingly cannot
4 establish proximate causation based upon her own self-serving testimony whether she
5 would have taken the drugs if warned. *See Sager v. Hoffman-La Roche, Inc.*, No. A-
6 3427-09T4, 2012 WL 3166630, at *15 (N.J. Super. Ct. App. Div., Aug. 7, 2012).
7 But even if she could, NPC would still be entitled to judgment as a matter of law
8 because Ms. Georges testified that she would have taken Aredia® in 1999 if warned
9 about ONJ. 4/18/2013 Trial Tr. 206:9-15; *see also id.* at 182:1-2 ("I'd like to say I
10 wouldn't take it, *but I would have taken it.*") (emphasis added). Ms. Georges did
11 testify – in sharp contrast to her deposition testimony – that she would not have taken
12 Zometa® in 2002 if warned because she "was already having the symptoms." *Id.* at
13 207:2-209:2. But as this Court previously recognized, "a refusal to take drugs that
14 have **already caused a medical condition** is entirely different from a refusal to take
15 drugs that **may make a medical condition more likely to occur.**" 11/2/12 Order
16 Denying Motion for Summary Judgment at 8 (ECF No. 189). "Plaintiff may not rely
17 on *post hoc* actions to predict hypothetical *ex ante* decisions." *Id.* Moreover, even
18 assuming Ms. Georges would have declined to take Zometa® in 2002, that decision
19 would not have prevented her injuries because she allegedly had already developed
20 her ONJ in March of 2000, two years earlier.

21 Plaintiff's second proximate causation theory, that a warning would have led
22 to a pre-treatment dental exam that in turn would have avoided her ONJ, is likewise
23 foreclosed by Dr. Waisman's trial testimony:

24
25 _____
26 ⁷ The Court held that NPC's duty to warn also ran to other of Ms. Georges'
27 physicians, i.e., her oral surgeons. 4/4/2013 Order at 11 (ECF No. 257).
28 Regardless, any such broader duty would not impact the decision whether to
prescribe Aredia® or Zometa®, particularly as the oral surgeons did not begin
treating Ms. Georges until after her jaw injuries appeared.

1 Q: Okay. And you were also asked questions about
2 how in 1999 you wished to very quickly treat the
3 cancer. If at that time you had been aware of a
4 relationship between ONJ and Aredia, would you
5 have -- would it -- would you have recommended
6 a dental exam before she went on the Aredia?

7 A: Probably not.

8 4/18/2013 Trial Tr. 99:2-7. Further, Plaintiff has presented no evidence that a pre-
9 treatment dental exam would have prevented her ONJ in any event. *See Payne*, 2013
10 WL 4779571, at *8 (“plaintiffs have offered no evidence to demonstrate a dental
11 exam would have prevented the onset of ONJ”). Indeed, Plaintiff visited her dentist
12 Dr. Barry Erbsen on June 24, 1999 – less than two months before her first Aredia®
13 infusion – for prophylaxis treatment, and there were no significant issues noted, and
14 so there was no basis in this record for anything but speculation as to what may or
15 may not have transpired had plaintiff made another pre-treatment visit. DX-1137, at
16 11. Plaintiff elected not to call Dr. Erbsen, and Dr. Sung offered no opinions about
17 even any hypothetical consequences of missing a pre-treatment dental exam in this
18 case. Accordingly, Plaintiff has no evidence to support this theory of proximate
causation.

19 Plaintiff failed to present sufficient evidence to satisfy her burden of proof on
20 proximate causation. For this reason as well, NPC is entitled to judgment as a
21 matter of law.

22 **C. Plaintiff Cannot Avoid Judgment As A Matter of Law Based
23 On An Exacerbation Or “Loss of Chance” Theory.**

24 At trial, Plaintiff argued that she could establish proximate causation by
25 proving that she and her doctor could have taken steps to avoid the extent of her
26 injuries had NPC adequately warned. This argument fails for three reasons:

27 First, Plaintiff abandoned her exacerbation or “loss of chance” theory prior to
28 trial when she elected not to oppose NPC’s motion in limine on this exact point,

arguing:

Defendant Novartis Pharmaceuticals Corporation (“NPC”) anticipates that plaintiff, in an effort to establish liability, may argue or present evidence suggesting that, as a result of NPC’s alleged failure to provide adequate warnings, Ms. Georges lost a chance to avoid ONJ or otherwise have a more favorable outcome with regard to her jaw problems. For example, plaintiff may argue that if Ms. Georges had known of the risk of ONJ she would have (1) stopped receiving bisphosphonates earlier, (2) received lower-dose or less frequent infusions of bisphosphonates, or (3) avoided certain dental extractions, and thereby improved her chances for a more favorable outcome. Plaintiff will likely argue further that, if she had taken these alleged risk-mitigating precautions, she may have had a better outcome with respect to her jaw – all without establishing within a reasonable medical probability that such precautions would have *actually* prevented her injuries.

Such arguments have no merit. As discussed below, “loss of chance” is not a viable theory of recovery under California law, and the Court should exclude all evidence and argument to support this improper theory.

Motion in Limine [No. 4] to Exclude Evidence and Argument Regarding Plaintiff's Loss of Chance for a More Favorable Outcome at 2 (ECF No. 150-1).

Plaintiff filed a non-opposition, stating: "Having conferred with co-counsel and read NPC's Motion in Limine No. 4, Plaintiff's counsel will agree to refrain from admitting evidence or making argument regarding Plaintiff's loss of a chance

1 for a more favorable outcome.” Plaintiff Adriann Georges’ Non-Opposition to
2 Motion in Limine to Exclude Evidence and Argument Regarding Plaintiff’s Loss of
3 Chance for a More Favorable Outcome at 2 (ECF No. 186).

4 This stipulation precludes Plaintiff from relying on a “loss of chance” or
5 exacerbation theory to satisfy her proximate causation burden. *See CDN Inc. v.*
6 *Kapes*, 197 F.3d 1256, 1258-59 (9th Cir. 1999) (party’s stipulation on issues that
7 would be addressed in case barred it from litigating other issues); *see also In re*
8 *Consol. Pioneer Mortgage Entities*, 91 F.3d 151, slip op. at *1 (9th Cir. 1996)
9 (unpublished) (“voluntary stipulation may estopp party from asserting a claim”)
10 (citing *Denco Dev. Co. v. Community Sav. & Loan Ass’n*, 376 F.2d 548, 551 (9th
11 Cir. 1967)); *Nichia Corp. v. Seoul Semiconductor Co.*, No. C 06-0162, 2007 WL
12 2533729 (N.D. Cal. Aug. 31, 2007) (same).

13 Second, and the presumptive predicate for Plaintiff’s stipulation, California
14 courts have routinely rejected loss-of-chance arguments. *See Dumas v. Cooney*,
15 235 Cal. App. 3d 1593, 1606-11, 1 Cal. Rptr. 2d 584, 591-94 (1991); *see also*
16 *Kuehn v. Children’s Hosp.*, 119 F.3d 1296, 1298 (7th Cir. 1997) (“California does
17 not recognize the loss of a chance doctrine”). “The recognition of a lost chance as a
18 cognizable injury is necessarily based on the reasoning that but for the defendant’s
19 negligence, the plaintiff *might possibly* have avoided an adverse result. Thus,
20 recognition of lost chance as a recoverable interest contradicts the very notion of
21 cause in fact.” *Dumas*, 235 Cal. App. 3d at 1609-10, 1 Cal. Rptr. 2d at 593. For
22 this reason, the loss of chance doctrine has been uniformly rejected in California as
23 “contrary to sound logic, legal precedent and public policy.” *Simmons v. West*
24 *Covina Med. Clinic*, 212 Cal. App. 3d 696, 705-06, 206 Cal. Rptr. 772, 778 (1989).

25 During closing arguments, Plaintiff made no effort to hide the fact that she
26 was relying on the loss-of-chance doctrine as a pathway to her exacerbation claim,
27 as her counsel repeatedly argued that NPC’s failure to warn deprived Ms. Georges
28 of her ability to make an “informed choice” regarding her cancer treatments that

1 could have lessened the extent of her injuries. *See* 4/22/2013 Trial Tr. 42:9-12
2 (“And what’s this case about? Well, it’s about Ms. Georges and her informed
3 patient choice, whether she gets to make her own decisions about her own health
4 care or whether Novartis does.”); *id.* at 75:15-76:4 (Ms. Georges “could have taken
5 less of Aredia and Zometa . . . she could have stopped at any time. . . . And if you
6 remember Dr. Sung, look, a lower amount of infusions isn’t a huge problem. We
7 can usually manage it.”); *id.* at 76:6-12 (“March of 2000, remember that date.
8 She’s got exposed bone, she has swelling, her problems begin. But she’s only had a
9 few doses of the drug. If Novartis had done its job, they would have known what
10 they knew later, and she could have gone off the drug just like she did when she
11 found out about this. She could have avoided all these tooth pulls and
12 debridements and all the rest of it.”); *id.* at 76:21-24 (“She could have stopped then,
13 or like in this case maybe Dr. Waisman would have convinced her to have two
14 more, three more . . .”). Plaintiff’s argument that Ms. Georges’ injuries could
15 have been reduced if she had been given the opportunity to make an “informed
16 choice” – because she would have received less bisphosphonates or avoided certain
17 dental procedures – is a classic loss-of-chance argument. Because California
18 rejects such a theory, it is insufficient as a matter of law to support a verdict against
19 NPC.

20 Third, Plaintiff failed to present sufficient evidence to support her proposed
21 exacerbation theory of proximate causation. In order to prove a causal link between
22 the alleged failure to warn and any exacerbation of her jaw problem, Plaintiff was
23 required to (1) establish that her treatment after March 2000 would have changed
24 with a different warning, and (2) provide expert testimony, to a reasonable degree
25 of medical probability, that the altered treatment would have resolved or reduced
26 the severity of her injuries. *See Latiolais*, 302 F. App’x at 757, 2008 WL 5157705;
27 *Motus*, 358 F.3d at 660-61; *Motus*, 196 F. Supp. 2d at 991; *Ingram*, 2012 WL
28 2922716, at *4. Plaintiff offered two arguments in support of her exacerbation

1 theory at trial: (1) that she would have discontinued or received less frequent
2 administrations of bisphosphonates at some point and (2) that she would have
3 avoided certain dental procedures. *See* 4/22/2013 Trial Tr. 75:9-23 (closing
4 argument by J. Vecchione). But she failed to satisfy her burden of proof on either.

5 Plaintiff's "duration of therapy" exacerbation theory rested initially upon the
6 proposition that Dr. Waisman would have changed Ms. Georges dosing schedule or
7 discontinued her Aredia® and Zometa® treatment at an earlier date if he had
8 received a different warning. But while Dr. Waisman testified that he now may
9 decrease the frequency of bisphosphonate administrations for some patients,
10 4/18/2013 Trial Tr. 33:20-35:2, there is no evidence that he would have changed Ms.
11 Georges' treatment in any way with a different warning. Plaintiff's counsel did not
12 ask that question of Dr. Waisman, and the jury could not have answered the question
13 itself, without gross and improper speculation. *See Motus*, 196 F. Supp. 2d at 997
14 (granting summary judgment on proximate causation grounds where plaintiff failed to
15 ask treating physician whether drug warning would have changed treatment).
16 Moreover, even though Ms. Georges testified that she would have been on the lookout
17 for symptoms, 4/18/2013 Trial Tr. 181:17-182:5, there is no evidence that this actually
18 would have resulted in a change in her drug treatment. Finally, Plaintiff has provided
19 no expert testimony to establish that any particular change in her Aredia® or Zometa®
20 treatment would have prevented (or reduced) Ms. Georges' ONJ injuries.⁸ The

21
22 ⁸ This Court required NPC to show that Ms. Georges received benefits from her use
23 of bisphosphonates and that plaintiff could have mitigated her injury. *See*
24 4/19/2013 Trial Tr. 48:19-56:1 (requiring expert testimony made to a reasonable
25 degree of medical probability regarding Ms. Georges *specifically*). For example,
26 NPC elicited testimony from Drs. Marx and Sung that smoking exacerbates wound
27 healing, in general. The Court ruled that such evidence was insufficient to support
28 NPC's defense because it did not establish, to a reasonable degree of medical
probability, that *Ms. Georges* actually would have reduced the severity of her injury
if she had stopped smoking. *See generally id.* at 53:17-55:1; *see also id.* at 54:20-
23 ("There is no doctor in this case who testified that if she would have ceased

1 limited testimony that plaintiff's obtained from her experts on this issue was not
2 specific to Ms. Georges. *See* 4/16/2013 Trial Tr. 50:24-51:15 (Dr. Sung); *id.* at
3 184:21-186:14 (Dr. Marx).

4 Without plaintiff-specific expert testimony, Plaintiff cannot prevail under this
5 theory of liability. *Jones*, 163 Cal App. 3d at 402, 209 Cal. Rptr. at 460-61 (“The
6 law is well settled that in a personal injury action causation must be proven within a
7 reasonable medical probability based upon competent expert testimony. Mere
8 possibility alone is insufficient to establish a *prima facie* case.”). Indeed, other
9 Aredia®/Zometa® courts have precluded plaintiffs’ dose and duration arguments as
10 speculative where, as here, there is no expert testimony that a different dosing
11 schedule or duration of treatment would have had any impact on the plaintiffs’
12 injuries. *See, e.g.*, Trial Tr. at 891:3-892:23, *Hill v. Novartis Pharm. Corp.*, No.
13 1:06-cv-00939 (E.D. Cal. June 18, 2013) (excluding testimony from fact witness
14 regarding dosing because “jury really wouldn’t have a basis for meaningfully
15 correlating this with any of the testimony of your experts”) (Ex. 2); Chambers
16 Conference Tr. at 28:12-30:3, *Mahaney v. Novartis Pharm. Corp.*, No. 1:06-CV-
17 35-R (W.D. Ky. Jan. 17, 2012) (same) (Ex. 3).

18 Plaintiff’s “avoidance of dental procedures” exacerbation theory fails for
19 much the same reasons. Although Plaintiff self-servingly testified that she would
20 have avoided certain oral surgeries if she had known of the risk of ONJ earlier,
21 4/19/2013 Trial Tr. 12:7-23, there is no evidence in the trial record regarding whether
22 any of these surgeries were in fact avoidable as a dental matter. *See Zimmerman*, 287

23
24 smoking that her condition would have improved or she would have -- it would
25 have been less severe.”); *id.* at 55:12-18 (“in order to support the giving of a
26 mitigation instruction you have to have the expert testimony to support that if -- if
27 the plaintiff would have done something or not have done something that would
28 have improved her condition, and that's a statement made by an expert and the
opinion is offered to a reasonable degree of medical certainty, then the instruction
would be given.”).

1 F.R.D. at 361 (granting summary judgment to NPC in Aredia®/Zometa® case where
2 dental extraction was unavoidable); *Eberhart*, 867 F. Supp. 2d at 1254-56 (same).
3 Ms. Georges' oral surgeon, Dr. Keith Radack, was the only witness who could have
4 testified to this, and Plaintiff elected not to call him. *See Motus*, 196 F. Supp. 2d at
5 997. More importantly, even assuming that certain dental procedures could have
6 and would have been avoided, Plaintiff has provided no expert testimony, to a
7 reasonable degree of medical probability, that Ms. Georges' ONJ would have
8 resolved or been less severe as a result of such measures. Again, without this
9 evidence, this exacerbation argument is unavailing. *See* 6/24/13 *Hill* Trial Tr.
10 1542:12-18 (granting Rule 50(a) motion and stating "we didn't hear, for example,
11 from anyone who has said, well, I'm an expert in this area, and if I had known this,
12 I would have advised Miss Hill to take -- to do the following dental treatment
13 differently from what she did, and I would have -- in my expert opinion, that would
14 have led to different -- better results for her jaw. None of that was present in this
15 case") (Ex.2); *see also Latiolais*, 302 F. App'x at 757; *Motus*, 358 F.3d at 660-61;
16 *Jones*, 163 Cal App. 3d at 402, 209 Cal. Rptr. at 460-61.

17 **D. Plaintiff Failed To Present Reliable Expert Evidence In Support
18 Of Specific Causation.**

19 Plaintiff cannot prevail on any of her claims unless she meets her burden of
20 proof on specific causation, *i.e.*, that Plaintiff's use of Aredia® or Zometa®
21 medically caused her to develop ONJ. To meet this burden at trial, Plaintiff relied
22 exclusively on the expert testimony of Dr. Eric Sung, who purported to opine on
23 specific causation based upon a differential diagnosis of Ms. Georges.⁹ Dr. Sung,
24 however, failed to conduct a scientifically reliable differential diagnosis and based
25 his opinion on insufficient facts and data. (It is also notable that plaintiff's lawyers
26

27 _____
28 ⁹ *See* 11/2/2012 Order at 6 (ECF No. 188) ("Plaintiff further argues . . . that Dr.
Sung did in fact perform differential diagnosis here")

1 drafted Dr. Sung's expert report for him. *See* 4/16/2013 Trial Tr. 78:15-86:6.) His
2 testimony should have been excluded, and it is in any event not sufficient to satisfy
3 Plaintiff's burden of proof. For this reason as well, NPC is entitled to judgment as
4 a matter of law.

5 This court's analysis of Dr. Sung's specific causation methodology is
6 governed by *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003). In
7 *Clausen*, the Ninth Circuit explained that “[t]he first step in the diagnostic process
8 is to compile a comprehensive list of hypotheses that might explain the set of
9 salient clinical findings under consideration.” *Id.* at 1057. Once the expert “rules
10 in” all potential causes, he or she next engages in a process of elimination:

11 After the expert rules in all of the potential hypotheses
12 that might explain a patient's symptoms, he or she must
13 then engage in a process of . . . eliminating hypotheses on
14 the basis of a continuing examination of the evidence so
15 as to reach a conclusion as to the most likely cause of the
16 findings in that particular case.

17 *Id.* at 1058. “[E]xpert testimony that neglects to consider a hypothesis that might
18 explain the clinical findings under consideration may . . . be unreliable. Including
19 even rare entities in the list ensures that such disorders are not overlooked.” *Id.*
20 (internal quotations omitted). Similarly, an expert cannot rule out competing
21 hypotheses on a mere *ipse dixit*, but rather “must provide reasons for rejecting
22 alternative hypotheses ‘using scientific methods and procedures,’” and must justify
23 the elimination of such hypotheses with “more than ‘subjective beliefs or
24 unsupported speculation.’” *Id.* (*quoting Claar v. Burlington N.R.R. Co.*, 29 F.3d
25 499, 502 (9th Cir. 1994)). If an expert fails to perform a differential diagnosis in
26 this manner, the district court is justified in excluding that expert's testimony. *Id.*
27 (*citing Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001)).

28 Courts within the Ninth Circuit have repeatedly excluded expert causation

1 testimony where testifying physicians have failed to employ a proper differential
2 diagnosis methodology. *See, e.g., Morin v. United States*, 244 F. App'x 142, 143-
3 144, 2007 WL 2112794 (9th Cir. 2007); *Whisnant v. United States*, 274 F. App'x
4 536, 537, 2008 WL 1775430 (9th Cir. 2008); *Nelson v. Matrixx Initiatives*, No. 09-
5 2904, 2012 WL 3627399, at *6-12 (N.D. Cal. Aug. 21, 2012); *Avila v. Willits Env'tl.*
6 *Remediation Trust*, No. 99-3941, 2009 WL 1813125, at *22-23 (N.D. Cal. June 18,
7 2009), *aff'd*, 633 F.3d 828 (9th Cir. 2011); *Heck v. City of Lake Havasu*, No. 04-
8 1810, 2006 WL 2460917, at *8-11 (D. Ariz. Aug. 24, 2006).

9 Courts presiding over Aredia® and Zometa® cases – both within and outside
10 of the Ninth Circuit – have reached the same conclusion. *See, e.g., Messick v.*
11 *Novartis Pharm. Corp.*, 924 F. Supp. 2d 1099, 1105 (N.D. Cal. 2013) (excluding
12 expert's specific causation testimony where he failed to rule out five alternative risk
13 factors); *Luttrell*, 894 F. Supp. at 1338-39 (excluding specific causation opinion of
14 expert because he failed to explain why alternative hypotheses as to causation were
15 ruled out); *Harvey v. Novartis Pharm. Corp.*, 895 F. Supp. 2d 1206, 1213 (N.D.
16 Ala. Oct. 4, 2012) (expert's "failure to give a reasonable explanation for concluding
17 that bisphosphonate drug use rather than osteomyelitis caused [plaintiff's] injury
18 renders his differential diagnosis not sufficiently reliable"); *see also Simmons v.*
19 *Novartis Pharm. Corp.*, 483 F. App'x 182, 187-89, 2012 WL 2016249 (6th Cir.
20 2012) (affirming exclusion of specific causation testimony by non-retained expert
21 in part because he did not rule out osteomyelitis as the sole cause of plaintiff's
22 ONJ).

23 Dr. Sung's testimony at trial clearly demonstrates that he did not conduct a
24 reliable differential diagnosis in this case. Indeed, he disclaimed performing a
25 differential diagnosis at all. 4/16/2013 Trial Tr. 86:7-9. Thus, while Dr Sung
26 acknowledged that there are alternative causes to ONJ, *id.* at 93:19-94:3, he
27 conceded that he considered only bisphosphonates as a potential cause of Ms.
28 George's ONJ:

Q Now you did not consider any other risk factors for osteonecrosis of the jaw that Ms. Georges had, other than her history of bisphosphonates, correct?

A Correct.

5 4/16/2013 Trial Tr. 92:23-93:1. Significantly, Ms. Georges has been diagnosed
6 with many ONJ risk factors, including, among others, osteomyelitis, poor dental
7 hygiene, tooth abscess, cancer, chemotherapy, steroids, smoking, obesity, and
8 vitamin D deficiency. *See generally id.* at 94:7-122:19. Dr. Sung testified that
9 some of these risk factors can independently cause necrotic bone in the jaw, while
10 others increase the risk of ONJ. *Id.* But he considered none of them in reaching his
11 causation opinion.

12 Dr. Sung’s failure to employ a reliable methodology to determine the cause
13 of Ms. Georges’ ONJ is consistent with the fact that his focus was on the *treatment*
14 of her jaw condition, *not determining its cause*. See *id.* at 141:19-22 (“I think at
15 that point in time I looked at it as we have this condition; I’m not going to go back
16 and say, ‘What caused it?’ My goal is to cure it or try to treat it.”). But “[t]he
17 ability to diagnose medical conditions is not remotely the same . . . as the ability to
18 deduce . . . in a scientifically reliable manner, the causes of those medical
19 conditions.” *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 673 (6th Cir. 2010)
20 (alteration in original). Plaintiff’s reliance on Dr. Sung’s evaluation of Ms. Georges
21 as evidence of specific causation “conflates diagnosis with etiology, eliding the
22 distinction between [Ms. Georges] disease and what caused it.” *Id.* As a number of
23 courts have explained:

24 Getting the diagnosis right matters greatly to a treating
25 physician, as a bungled diagnosis can lead to unnecessary
26 procedures at best and death at worst. But with etiology,
27 the same physician may often follow a precautionary
28 principle: If a particular factor *might* cause a disease, and

1 the factor is readily avoidable, why not advise the patient
2 to avoid it?

3 *Id.* at 673 (citation omitted). “This low threshold for making a decision serves well
4 in the clinic but not in the courtroom, where decisions require not just an educated
5 hunch but at least a preponderance of the evidence.” *Id.*

6 By his own admission, Dr. Sung “neglect[ed] to consider [hypotheses] that
7 might explain the clinical findings under consideration,” and failed to rule out
8 alternative causes by “using scientific methods and procedures.” *Clausen*, 339 F.3d
9 at 1058. He has offered no basis for why or how he ruled out alternative causes for
10 Ms. Georges jaw injuries, other than his own untested *ipse dixit*. Indeed, he was
11 not even aware these alternative causes applied to Ms. Georges when he formulated
12 his opinions. These failures render Dr. Sung’s specific causation opinions
13 unreliable. *See Morin*, 244 F. App’x at 143-144, 2007 WL 2112794; *Whisnant*, 274
14 F. App’x at 537, 2008 WL 1775430; *see also Heller v. Shaw Indus., Inc.*, 167 F.3d
15 146, 156 (3d Cir. 1999) (“[W]here a defendant points to a plausible alternative
16 cause and the doctor offers *no* explanation for why he or she has concluded that it
17 was not the sole cause, that doctor’s methodology is unreliable.”); *Luttrell*, 894 F.
18 Supp. 2d at 1338-39 (excluding specific causation opinion of expert because he
19 failed to explain why alternative hypotheses as to causation were rule out).

20 Dr. Sung’s opinions are additionally unreliable because they are based on
21 insufficient facts or data. *See Fed. R. Evid. 702(b)*. Dr. Sung conceded that, when
22 performing any sort of differential diagnosis, it is important to know all of the
23 patient’s medical and dental history, so that the doctor can identify the right factors
24 to consider; that the more a doctor knows about a patient’s history, the easier it is to
25 reach a final diagnosis; and that for a patient presenting with an oral lesion, “if you
26 have a complete record for that patient it’s more likely that you would reach the
27 correct final diagnosis as to what caused the lesion.” 4/16/2013 Trial Tr. 88:19-
28 89:14. Yet, in this case, Dr. Sung rendered his opinions without *any* review of Ms.

1 Georges' medical or dental records for the more than six-and-a-half years she had
2 allegedly suffered from her ONJ injury *before* Dr. Sung's first treatment of her. *See*
3 *id.* at 89:18-81:13, 92:10-14; *see also* *Claussen*, 339 F.3d at 1049 (explaining that a
4 reliable differential diagnosis is typically performed "after physical examinations,
5 the taking of medical histories, and the review of clinical tests" (internal quotation
6 marks omitted)).

7 Because he did not review the records, Dr. Sung was unaware of much of
8 Ms. Georges' medical and dental history:

- 9 • He did not know whether Ms. Georges' jaw problem was related to a
10 dental procedure or whether it occurred spontaneously, nor did he ever
investigate this matter. 4/16/13 Trial Tr. 91:18-24.
- 11 • He did not know when Ms. Georges' exposed bone first developed,
12 and in fact was under the mistaken belief that it did not develop until
October 2004, more than four-and-a-half years after the date it actually
did. *Id.* at 92:2-9.
- 13 • He was not aware that Ms. Georges had been previously diagnosed
14 with osteomyelitis or treated for osteomyelitis, an infection of the jaw
bone which he admits can cause ONJ in the absence of
bisphosphonates. *Id.* at 93:15-18, 102:17-107:1. (Dr. Sung conceded
he was not an expert regarding osteomyelitis. *Id.* at 75:25-76:2.)
- 15 • He did not know anything about Ms. Georges' history of dental
16 surgery other than the fact that she had toothless regions the first time
he treated her, resulting from teeth either that were extracted or that
fell out. *Id.* at 31:4-11.
- 17 • He knew Ms. Georges had cancer and that she had received
18 chemotherapy and steroid treatments, but he did not look at the records
to determine the types of chemotherapy and steroid treatments she had
received in the past, or the dose or duration. *Id.* at 112:12-24. Dr.
Sung admitted that chemotherapy can cause ONJ, *id.* at 107:12-14, and
steroids are a risk factor for it, *id.* at 111:11-14.
- 19 • He did not know that Ms. Georges had been diagnosed with obesity,
20 vitamin D deficiency, or hyperglycemia, things that he admitted were
21 ONJ risk factors. *Id.* at 118:6-119:15, 122:17-124:15, 125:5-126:17.

22
23 As numerous courts have explained, the "performance of physical
24 examinations, taking of medical histories, and employment of reliable laboratory
tests all provide significant evidence of a reliable differential diagnosis, and . . .
25 their absence makes it much less likely that a differential diagnosis is reliable."

1 *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179 (6th Cir. 2009) (internal
2 quotation marks omitted); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th
3 Cir. 2001) (same); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 759 (3rd Cir.
4 1994) (same). Indeed, Dr. Sung's methodology in this case is virtually identical to
5 that of another expert witness whose specific causation testimony was recently
6 stricken after trial under California's *more liberal* state law rules for expert
7 admissibility. *See Cooper v. Takeda Pharm. Am., Inc.*, No. JCCP 4696, 2013 WL
8 1846220 (Cal. Super. Ct. May 1, 2013). In *Cooper*, an expert witness offered a
9 specific causation testimony without conducting a proper review of the plaintiff's
10 medical records and history and without reliably ruling out alternative causes. *Id.* at
11 5-7. The trial court initially allowed the expert to testify, and plaintiffs secured a
12 jury verdict. *Id.* at 2. After consideration of the expert's trial testimony, however,
13 the trial court granted defendant's motion to strike the expert's opinion. *Id.* at 11.
14 As the court explained in terms equally applicable here:

15 There is nothing in Dr. Smith's . . . testimony, which
16 demonstrates that Dr. Smith could disregard the identified
17 risk factors as they specifically relate to Mr. Cooper.
18 Again, a differential diagnosis is a *patient-specific*
19 process. . . . [I]nstead of his differential diagnosis being
20 patient specific, based upon a review of the patient's
21 medical history, clinical tests, biological and
22 physiological markers, and physical examination of the
23 patient, Dr. Smith rendered a diagnosis based upon
24 speculation, conjecture and leaps of logic.

25 *Id.* Because plaintiffs could not meet their burden of proof under California law
26 without expert testimony on specific causation, the court then granted defendant's
27 motion for nonsuit. *Id.* at 12. The same result is warranted here.
28

1 **II. If The Court Declines To Grant NPC Judgment On All Claims, The**
2 **Court Should, In The Alternative, Grant A New Trial And/Or Amend**
3 **The Judgment To Reduce Plaintiff's Damages Award.**

4 In the event the Court declines to grant NPC judgment as a matter of law on
5 all claims, NPC moves in the alternative, pursuant to Federal Rule of Civil
6 Procedure 59, for (1) a new trial based on the erroneous admission of Plaintiff's
7 improper exacerbation of injury arguments and/or (2) amended judgment to reduce
8 Plaintiff's award of non-economic damages.

9 **A. NPC is entitled to a new trial without evidence or argument in**
10 **support of an exacerbation theory that Plaintiff abandoned prior**
11 **to trial and that is impermissible under California law.**

12 As discussed above, Plaintiff's proximate causation argument at trial relied
13 heavily on the theory that, if Ms. Georges' physicians had received different
14 warnings after Ms. Georges developed ONJ, they would have had the chance to
15 take actions with regard to the dose and duration of the Aredia®/Zometa® therapy or
16 with regard to certain dental treatments that might have improved her clinical
17 outcome. The jury should never have heard this exacerbation evidence or
18 argument, however, because Plaintiff waived the argument in deciding not to
19 oppose NPC's pre-trial motion in limine and because the argument is barred under
20 California law. *See supra* Section I.C.

21 The Court's erroneous admission of Plaintiff's exacerbation evidence and
22 argument affected NPC's substantial rights and requires a new trial. In reviewing
23 the effect of erroneous evidentiary rulings, this Court must "begin with a
24 presumption of prejudice." *Obrey v. Johnson*, 400 F.3d 691, 701 (9th Cir. 2005).
25 The Court "must reverse . . . unless it is more probable than not that the error did
26 not materially affect the verdict." *Id.* Moreover, "the party benefitting from the
27 error has the burden of persuasion, and in cases of equipoise, we reverse." *Id.*
28 (internal quotation marks omitted); *see also Levi Strauss & Co. v. Abercrombie &*

1 *Fitch Trading Co.*, 633 F.3d 1158, 1174 (9th Cir. 2011) (following *Obrey*).

2 The Court cannot conclude that the erroneous admission of Plaintiff's
3 exacerbation evidence did not taint the jury verdict. "The evidence at issue was not
4 merely tangential or cumulative; rather, it was directly probative of the central
5 issues in dispute." *Obrey*, 400 F.3d at 701-02. Ms. Georges allegedly developed
6 ONJ in March 2000, years before NPC became aware of any information that could
7 have given rise to a duty to warn. Ms. Georges' prescribing physician (and Ms.
8 Georges herself) unequivocally testified that Ms. Georges would have received
9 Aredia® prior to the emergence of her jaw injuries even with full knowledge of the
10 ONJ risk. There is no evidence that a different warning would have resulted in any
11 change in Ms. Georges' medical treatment that would have avoided her ONJ.
12 Plaintiff's case thus rested heavily – if not entirely – on the erroneously admitted
13 evidence and argument that an earlier warning would have given Ms. Georges and
14 her physicians the chance to take steps that (allegedly) could have lessened the
15 severity of her ONJ.

16 Plaintiff cannot meet her burden of proof "that it is more probable than not
17 that the jury was unaffected" by the improper admission of this evidence and
18 argument. *Id.* at 702. Accordingly, if the Court does not grant NPC's motion for
19 judgment as a matter of law, NPC is entitled to a new trial.

20 **B. In the event the Court declines to order a new trial, the Court
21 should amend the judgment to reduce Plaintiff's economic
22 damages award**

23 Should the Court decline to grant NPC either judgment as a matter of law or
24 a new trial, the Court should amend the judgment to reduce Plaintiff's award for
25 past and future economic damages, because the current awards are not supported by
26 the trial record.

1. The Court should reduce Plaintiff's Award for past economic damages to \$50,000.

The jury awarded Plaintiff \$250,000 in past economic losses, a figure that is unsupported by the evidence adduced at trial. The Court should reduce it to conform to the evidence that was actually presented.

Under California law, an injured party “must establish by proof the extent of the harm and the amount of money representing adequate compensation with as much certainty as the nature of the tort and the circumstances permit.” *Clemente v. State*, 40 Cal. 3d 202, 219, 219 Cal. Rptr. 445, 455 (1985) (quotations omitted). “[D]amages which are speculative, remote, imaginary, contingent, or merely possible cannot serve as a legal basis for recovery.” *Piscitelli v. Friedenberg*, 87 Cal. App. 4th 953, 989, 105 Cal. Rptr. 2d 88, 113 (2001) (*quoting Frustuck v. City of Fairfax*, 212 Cal. App. 2d 345, 367-68, 28 Cal. Rptr. 257, 371 (1963)). When past medical expenses are sought – as they were in this case – “a plaintiff may recover as economic damages *no more* than the reasonable value of the medical services received and is not entitled to recover the reasonable value if his or her actual loss was less.” *Howell v. Hamilton Meats & Provisions, Inc.*, 52 Cal. 4th 541, 555, 129 Cal. Rptr. 3d 325, 334 (2011). “To be recoverable, a medical expense must be both incurred *and* reasonable.” *Id.*

Pursuant to Fed. R. Civ. P. 26(a)(1)(A)(iii) and the Case Management Order entered by the United States District Court for the Middle District of Tennessee, *In re Aredia and Zometa Prods. Liab. Litig.* (MDL 1760), No. 3:06-1760, at 32 (M.D. Tenn. July 28, 2006) (Ex. 4), plaintiff disclosed the economic damages she was seeking to recover in this case. See Pl.’s Fact Sheet at 25 (Request T and Response) (Ex. 5). In an attempt to resolve a dispute over some of these medical expenses sought by plaintiff, the parties stipulated that her past medical expenses were

1 50,000, and the Plaintiff testified to this figure.¹⁰ *See* PX-1182D; 4/18/2013 Trial
2 Tr. 180:2-181:10. This was the only evidence offered at trial regarding past
3 economic damages that were even possibly attributable to NPC's alleged
4 misconduct.

5 Plaintiff presented no other evidence regarding the cost of any other
6 reasonably necessary medical expenses, let alone any amount actually incurred by
7 Plaintiff or her insurance. Any award for past medical expenses exceeding this
8 amount is necessarily speculative, and should be stricken by the Court. *See*
9 *Piscitelli*, 87 Cal. App. 4th at 989, 105 Cal. Rptr. 2d at 113; *Frustuck*, 212 Cal.
10 App. 2d at 367-68, 28 Cal. Rptr. at 371; *Mozzetti v. City of Brisbane*, 67 Cal. App.
11 3d 565, 577, 136 Cal. Rptr. 751, 758 (1977) ("It is black-letter law that damages
12 which are speculative, remote, imaginary, contingent or merely possible cannot
13 serve as a legal basis for recovery"); Fed. R. Civ. P. 59(e).

14 **2. The Court Should Strike Plaintiff's Award for Future
15 Economic Damages in its Entirety.**

16 In addition to past economic damages, the jury awarded Plaintiff \$200,000 in
17 future economic losses. This award is speculative and should be stricken in its
18 entirety.

19 Under California law, "[t]o entitle a plaintiff to recover present damages for
20 apprehended future consequences, there must be evidence to show such a degree of
21

22 ¹⁰ Although Plaintiff elicited testimony from Ms. Georges that "the charge for
23 Zometa" was \$879.48, she provided no foundation for this statement, did not prove
24 that this was a cost that was actually incurred, and expressly represented to counsel
and the Court that "I am not going to seek damages for all the infusions."
4/19/2013 Trial Tr. 5:12-13; *see also id.* at 6:5-12 ("As Mr. Vecchione has
represented, he's not going to be arguing that he's entitled to recover that and I
think he's now indicated that testimony should be stricken. It probably would make
sense for the jury just to be told, 'You heard about the costs of infusions. The
plaintiff's not going to be seeking that, so you should disregard that testimony.'"
25 **The Court:** Yeah, I'll instruct the jury accordingly."). The Court then struck the
26 testimony about the total amount Ms. Georges had allegedly paid for her Aredia®
27 and Zometa® infusions. *Id.* at 9:8-10.

1 probability of their occurring as amounts to a reasonable certainty that they will
2 result from the original injury.” *Bellman v. San Francisco High Sch. Dist.*, 11 Cal.
3 2d 576, 588, 81 P.2d 894, 900 (1938); *see also Frustuck*, 212 Cal. App. 2d at 368,
4 28 Cal. Rptr. at 371 (“even where damages are recoverable for prospective
5 detriment, the occurrence of such detriment must be shown with such a degree of
6 probability as amounts to a reasonable certainty that such detriment will result from
7 the original injury.”). Damages that are speculative, contingent, or merely possible
8 cannot justify an award of future economic damages. *See Frustuck*, 212 Cal. App.
9 2d at 367-68, 28 Cal. Rptr. at 371.

10 In this case, Plaintiff provided no evidence regarding the anticipated future
11 evolution of Ms. Georges’ jaw injury, and no evidence regarding the reasonable
12 medical expenses that will be necessary to treat her condition. Dr. Sung testified as
13 to the *current* status of Ms. Georges’ jaw injury, noting that her left side has healed
14 completely, and her right side has improved, and currently has only a needle-point
15 bone exposure. 4/16/2013 Trial Tr. 37:9-38:20, 41:2-5. But Dr. Sung did not opine
16 regarding how long Ms. Georges’ injury is likely to remain, what treatments, if any,
17 Ms. Georges is likely to need, or the reasonable costs of such treatments. Without
18 this evidence, any jury award for future economic damages is necessarily
19 speculative, and should not be allowed.¹¹

20 For these reasons, the Court should amend the Judgment and strike the jury’s
21 award of \$200,000 in future economic damages.

22 ///

23 ///

24 //

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26

27 ¹¹ NPC had objected to the jury even being asked about future economic damages,
28 4/22/2013 Trial Tr. 16:16-17:1, but the Court overruled the objection, noting that
this issue could be reviewed if such damages were awarded, *id.* at 17:2-6.

CONCLUSION

For the reasons discussed above, the Court should grant NPC's Motion for Judgment as a Matter of Law on all claims. In the event the Court declines to do so, the Court should order a new trial, or in the alternative, amend the judgment to reduce Plaintiff's award for past and future economic damages.

DATED: October 22, 2013

PARKER, MILLIKEN, CLARK, O'HARA
& SAMUELIAN, APC
Richard A. Clark
Natasha N. Dawood

Bv: /s/Richard A. Clark

Richard A. Clark

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Novartis Pharmaceuticals Corporation

1 **EXHIBITS TO FOLLOW**
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